

# **SPL Process ER/DL Meeting**

## **Meeting Minutes**

### **July 16, 2014**

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

\*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

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Agenda:

#### 1. Update on SPL standards

- Update SPL R5 standard status
  - Passed as a normative standard.
  - In process for submitting to ANSI for approval
  - Stages: Draft....draft status for trial use (DSTU).... normative(fully approved)
  - We have been using R5 in DSTU status since 2010. So now R5 is fully approved.
  - No impact to current requirements for SPL now that it is normative.
- Overview SPL R6
  - To be balloted during the next cycle, starting August 8. If it passes, it will be R6. It will be balloted as normative. We expect that this would pass.
  - Don't know if this is a new doc type ...or new content to be added to current SPL.
  - Scope: to help support REMS, common product model (assumes related to IDMP model). Jointly sponsored by RCRIM and OandO (which models CPM).
    - REMS: SPL will support. Not sure how it would support. Hope that this would be further explained.
    - We could invite Gunther to this meeting to explain how REMS would be implemented.
    - Both standards would be incremented that would benefit SPL and potentially IDMP.
- SPL use for submitting UDI
  - HL7 Harmonization using UDI, review versus other stakeholders.

- HL7 wants to include these elements in the patient health record.

2. Recap DIA Annual Meeting (e.g., Drug Listing, Medical Device UDI, etc.)

- How to make a successful DER, drug listing, etc submission. 3 fda and Tom Bizarro
- Lots of existing info
- New info:
  - NDCs: more labeler codes will be needed because new labelers are being added and numbers available will run out.
    - One option is to use 10 digits – but expand labelers to 6 digits
  - 21CFR 207: Final rule release being planned for 2015
  - New online web forum CDER Direct
- Lonnie talked about
  - Common errors
  - Gave category of recent validation procedures: DUNS,
  - Combination products: needs to be in CBER now....and in CDER products starting Sept 1, 2014.
  - NLM Daily Med now has over 62,000 SPLs.
- Tom Bizzaro-downstream uses:
  - Allows aggregating of information
- CDRH session:
  - Future: INDRForum

3. How companies are handling what seems to be an influx of FDA requests for revised formatting of MS Word documents that cause misalignment with the unaltered SPL stylesheet?

- For example, underlining of level 3 headers. Without manipulating the SPL stylesheet (which I think is the FDA/SPL staff's preference) the level 3 headers are unbold no underline.
- Several companies are seeing more requests for style changes – formatting and styles that haven't been seen before. These style requests are not in the regulations.
  - More underlining and italics.
  - Trying to limit numbering in section 17 (few subsections, use bullets)
  - (in PLR guidance, make sure consistent with the 42 points in the PI formatting checklist). But getting comments on 3<sup>rd</sup> and 4<sup>th</sup> level hierarchy.
  - <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/UCM373025.pdf>

4. Generic names – which one to use throughout the document. Active ingredient or active moiety? Howard Shatz

- No one has had this situation

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REMINDERS:

- SPL Jamboree 2014: National Library of Medicine has announced the 2014 SPL/DailyMed Jamboree Workshop which is scheduled for September 18, 2014, at NLM in Bethesda, MD. More information (including the agenda) regarding this free public SPL workshop is posted on this NLM web page: [http://www.nlm.nih.gov/mesh/spl\\_workshop\\_2014.html](http://www.nlm.nih.gov/mesh/spl_workshop_2014.html).
- Sept 1, 2014 – Implementation of “Combination Product Type” data element for CDER-regulated products

1. SPL Jamboree 2014:

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**Meeting discussion:**